

# The effectiveness of HABIT-ILE method in water to rehabilitate children with unilateral spastic cerebral palsy

## INTRODUCTION

**Definition**

Cerebral Palsy (CP) affects approximately 17 million children worldwide the most common cause of physical disability in children:

- Group of motor control disorders that develops through different abnormalities of posture, muscle tone and motor coordination
- Congenital lesion that affects the immature brain

Different types of Cerebral Palsy

**Justification**

- Becoming known
- In Pubmed, only 5/18 are good concerning HABIT-ILE
- In Pedro, only 1 article, 6/10
- HABIT-ILE method improves the motor function of upper and lower limbs
- New type of intensive rehabilitation
- Balneotherapy sessions because it's effective for postural control and pain

**Epidemiology**

Cerebral Palsy affects today 2% births: approx. 1 500 new cases/year in France ; about 700,000 births in France each year

Risk Factors	Protecteur Factors	Confounding Factors
- Born prematurely	- Magnesium sulfate	- Ethics
- Birth weight very low	- Caffeine	- Socioeconomic status
- Infection	- Corticosteroid	- Small genetic and metabolic diseases
- Perinatal asphyxia		
- Stroke		
- HIV		
- Toxic factors		

**Objective**

Evaluate the effectiveness of HABIT-ILE in the water for children with unilateral spastic palsy, with children aged 6 to 12 years

**Specific Objectives**

Analysis of the walk, endurance, of the range of motion, of the pain, of the spasticity, and of the activity of the upper and lower limbs

**HABIT-ILE**

Hand and Arm Bimanual Intensive Therapy Including Lower Extremities)

- New method
- Constant stimulation of the upper and lower extremities
- Game to improve children's autonomy and coordination
- Small groups, 10 days, 90 hours
- The children are volunteers

**Hypothesis**

HABIT-ILE in water method has better results in daily tasks in children with unilateral spastic cerebral palsy than the conventional HABIT-ILE method

## DESIGN AND METHOD

**Type of study:** Prospective, randomized, controlled, experimental clinical trial with two parallel groups - Single-blind study  
 Patients do not know in which groups they are in, but they are not blind - Physical therapists and parents are not blinded either - Analysis are blinded

**Randomization:** Participants are randomized, simple randomization procedures, two groups (control / intervention)

**Study duration:** 12 months, 15 days intervention, 10 days of training, 90 hours, 9 hours per day

**Treatment volume:** Similar between the two groups, the parameter is to distinguish sessions in water and classical sessions

**Investigators:** 19 physiotherapists, 19 interns, 4 analysts, 1 researcher, 2 doctors

### Study population

38 patients selected. 19 patients in each group. The study is being carried out in France, in two different locations (no overlapping between the control and intervention groups)

- Control group: vacation center in Palavas (IGESA)
- Intervention group: Institut Saint-Pierre (including a balneotherapy for the children)

### Patient selection

- Patients must be contacted by their doctor or by a hospital
- Must complete the consent form, and read and sign the study information sheet
- Must return the consent form and the signed information sheet
- Must meet the inclusion and exclusion criteria
- Randomization will be done and they will receive an email to know if they are in group A or B
- Valuation of the study variables by the physician

#### Inclusion Criteria

- Unilateral spastic cerebral palsy
- Cerebral palsy between grade 2 and 3, must be diagnosed and confirmed by a physician
- Have not previously participated in the HABIT-ILE method
- Able to follow instructions, and listen to them, a doctor must confirm it
- Children (6 and 12 years old)
- Ability to raise the most affected arm 15cm above a table surface
- Have a grade level equal to that of their peer
- Children must score between 6 (independent on all surfaces) and 2 (uses Kaye walker or frame) on the Functional Mobility Scale which is completed by the parents

#### Exclusion Criteria

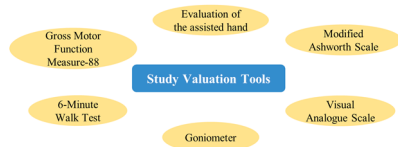
- No dystonia
- No botulinum toxin injection within 6 months prior to study
- Untreated seizures
- No intense therapy within 6 months prior the study
- No planned orthopedic surgery, nor have had any surgery in the past 12 months
- No health problems unrelated to Cerebral Palsy
- No vision or cognitive problems, as this could interfere badly with the treatment
- Not accepted if parents are unwilling to consent to the child's Participation

### Description of the intervention

- Analyze the effectiveness of balneotherapy associated with the HABIT-ILE - Evaluate the effects on the chosen variables and make comparison with the control group
- All days start at 8 am and end at 6 pm, with one hour lunch break
- Intervention group starts with two hours of balneotherapy, then another two hours in the early afternoon and has conventional HABIT-ILE method the rest of the day
- Both groups work on upper limbs in the morning and lower limbs in the afternoon
- All day long, they play indoor and outdoor games
- Daily report by the physiotherapists sent to the analysts and the physical therapist researcher

### Dependent and Independent variables

According to the Function	Study variable	According to the nature	According to the values	Tools
DEPENDENTE	Treatment	Qualitative	Nominal	Control : method HABIT-ILE
		Qualitative	Nominal	Intervention: Method HABIT-ILE + sessions in the water
DEPENDENTE	Walk	Quantitative	Discrete	6 minutes walk test (6MWT)
	Movement Rank	Quantitative	Discrete	Goniometer
	Pain	Quantitative	Discrete	Visual Analogue Scale (VAE)
	Spasticity	Quantitative	Discrete	Modified Asworth Scale (MAS)
	Activity of the upper limbs	Qualitative	Ordinal	Assisting Hand Assessment (AHA)
	Activity of the lower limbs	Qualitative	Ordinal	Gross Motor Function Measure (GMFM-88)



### Data Collection

Table 1. Description of the sample at the beginning of the study and comparison of the initial similarity.

	Habit-ile Group (n=19)	Habit-ile+Aquatic Group (n=19)	Valor-P
<b>Quantitative variables</b>			
Age (years)			
Range of motion			
Hip Extension			
RE Hip			
Abduction hip			
Knee Extension			
HG Extensors			
HG Abductors			
RE GH			
Elbow Extensors			
Wrist Extensors			
6MWT (M)			
Pain (EVA)			
MAS			
<b>Categorical variables</b>			
n	(%)	n	(%)
Sex			
Men			
Women			
affected side			
Left			
Right			
dominant side			
Left			
Right			
Grade Cerebral Palsy			
Grade 2			
Grade 3			
Grade 4			
GMFM-88			
AHA			

SD: Standard deviation. P-value: Statistical significance. \*p<0.05 \*\*p<0.001. n= number of participants.

## INVOLVEMENT

### Results

- We expect to have a statistically significant difference (p < 0.05) in the G.I compared to the G.C.
- Comparison G.I. vs. G.C.
- Validation of the hypothesis : the treatment with the sessions in water improves the variables that we have chosen to evaluate

Table 2. Time-dependent analysis of dependent variables in the control group.

	Baseline	T0	T1	T2	T3	T4	T5	T6
Range of motion								
Hip Extension								
RE Hip								
Abduction hip								
Knee Extension								
HG Extensors								
HG Abductors								
RE GH								
Elbow Extensors								
Wrist Extensors								
6MWT (M)								
Pain (EVA)								
MAS								
GMFM-88								
AHA								

SD: Standard deviation. P-value: Statistical significance. \*p<0.05 \*\*p<0.001. T0: Measurement taken before the intervention, T1: Measurement taken at the end of the intervention, T2: Measurement collected at 1 month, T3: Measurement collected at 2 months, T4: Measurement collected at 3 months, T5: Measurement collected at 4 months, T6: Measurement collected at 5 months.

Table 3. Time-dependent analysis of dependent variables in the Habit-ile+Aquatic group.

	Baseline	T0	T1	T2	T3	T4	T5	T6
Range of motion								
Hip Extension								
RE Hip								
Abduction hip								
Knee Extension								
HG Extensors								
HG Abductors								
RE GH								
Elbow Extensors								
Wrist Extensors								
6MWT (M)								
Pain (EVA)								
MAS								
GMFM-88								
AHA								

SD: Standard deviation. P-value: Statistical significance. \*p<0.05 \*\*p<0.001. T0: Measurement taken before the intervention, T1: Measurement taken at the end of the intervention, T2: Measurement collected at 1 month, T3: Measurement collected at 2 months, T4: Measurement collected at 3 months, T5: Measurement collected at 4 months, T6: Measurement collected at 5 months.

### Discussion

- HABIT-ILE and balneotherapy are two methods that are conclusive and work well
  - These two methods have never been done together
  - The literature shows that HABIT-ILE improve some variables significantly
  - Thanks to balneotherapy other variables also improve
- By combining these two methods we expect to have very good results

### Limitations

- The children do not sleep in the center
- Pairings are made however cerebral palsy varies greatly from one child to another
- Parents do not participate to the study
- The sessions in the water can be very tiring and therefore some children could more easily abandon the study

### Strengths

- HABIT-ILE is a new method but it gives very good results
- Balneotherapy is an older method that also gives very good results
- HABIT-ILE is a non-invasive method
- The course does not last long, only two weeks
- The children are followed by the same physiotherapist, and they are alone with the physiotherapist

## REFERENCES

Bleyenheuff Y, Arnould C, Brandao MB, Bleyenheuff C, Gordon AM. 2015. Hand and Arm Bimanual Intensive Therapy Including Lower Extremity (HABIT-ILE) in Children With Unilateral Spastic Cerebral Palsy: A Randomized Trial. *Neurorehabil Neural Repair.* 29(7):645-57.

Bleyenheuff Y, Ebner-Karacsoni D, Surana B, Parada J, Sidropoulos A, Rinders A, et al. 2017. Intensive upper- and lower-extremity training for children with bilateral cerebral palsy: a quasi-randomized trial. *Dev Med Child Neurol.* 59(6):625-33.

Billington SJ, Naidoo R. 2018. The carry-over effect of an aquatic-based intervention in children with cerebral palsy. *African J Disabil.* 7:1-8.

Graham HK, Rosenbaum P, Paineo N, Dun B, Lin JP, Damiano DL, et al. 2016. Cerebral palsy. *Nat Rev Dis Prim.* 2:1-24.